IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: WALLACH=25

In re Application of:	)	Conf. No.: 7328
David WALLACH	)	Art Unit: 1636
Appln. No.: 09/671,687	)	Examiner: D. Lamberton
Filed: September 28, 2000	)	Washington, D.C.
For: NOVEL INHIBITOR OF NF-KB ACTIVATION	)	September 25, 2003

RESPONSE

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

OK To enter DJ 10/20/03

Sir:

The present communication is responsive to the official action of June 25, 2003. Claims 2-4, 20-24 and 38-46 presently appear in this case. No claims have been allowed, although claims 3 and 44-46 have been indicated to be allowable if rewritten in independent form. The official action of June 25, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a protein comprising the amino acid sequence of SEQ ID NO:3, a variant of SEQ ID NO:3 which has at least 85% identity therewith, more preferably at least 90% identity and most preferably at least

95% identity, or a fragment of SEQ ID NO:3, or a variant thereof, all of which are capable of binding to TRAF2. The present invention further relates to compositions comprising such proteins and antibodies capable of binding thereto.

The interview among examiners Lamberton and Guzo, Technology Center Practice Specialist, Elliot, and the undersigned, on September 23, 2003, is hereby gratefully acknowledged. In this interview, the written description issue was discussed, particularly with respect to example 14 of the training materials for the written description guidelines. As a result of this interview, agreement was reached that if applicant would request reconsideration of this rejection, it would be withdrawn. However, the examiner would consider issuing a new non-final office action containing an enablement rejection.

Claims 2, 4, 20-24 and 38-43 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The examiner states that example 14 of the written description training materials is not applicable because applicant has not described a procedure for making variants which retain the functionality of the claimed sequence. This rejection is respectfully traversed.

The examiner's argument predominantly relies on the statement at the bottom of page 53 of the written description training materials that states:

> Moreover, procedures for making variants of SEQ ID NO:3 which have 95% identity to SEQ ID NO:3 and retain its activity are conventional in the art.

The examiner interprets this as requiring that the specification disclose a way to predict which of the variants retain activity. However, it is urged that this sentence does not have the meaning that the examiner ascribes to it. Nowhere in this example does it state that in applicant's specification there was an indication of which regions can or cannot be changed. Furthermore, this sentence cannot refer to the specification, as it talks about what is "conventional in the art". As this sentence follows the statements that procedures for making variants are conventional in the art and an assay is described, the proper interpretation is that, because procedures for making variants are conventional in the art and an assay is described, it is conventional in the art to determine which of the variants of SEQ ID NO:3 retain its activity. There is nothing to suggest that this adds anything to the example other than what is otherwise stated there. Indeed, this should be clear from the last sentence on page 54, which states:

> The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3, which are capable of the specified catalytic activity.

It is thus clear from the conclusion that it is the assay which is all that is necessary to provide adequate written description for the entire genus of compounds having 95% structural identity and retained catalytic activity.

After discussing this issue back and forth, the technology center practice specialist, George Elliot, confirmed that it was not the intent of the drafters of example 14 to require the type of explanation of the nature of every region of the protein in order to comply with the written description requirement. Accordingly, for these reasons and for all of the reasons set forth in applicant's amendment of April 4, 2003, applicant again respectfully requests that this rejection be reconsidered and withdrawn.

With respect to the portion of the claim relating to fragments, it should be noted that the wherein clause at the end of claim 2 requires that said fragments be capable of binding to TRAF2. Fragments only involve deletions from the N or C terminal. They do not involve substitutions or insertions. Accordingly, the universe of possible fractions

within the genus of claim 2(c) is much smaller than the universe of possible variants within the genus of 2(b). If the genus of 2(b) is found to have written description in view of example 14, then certainly the much smaller genus of fragments of 2(c) must also comply with the written description requirement. It is routine to produce fragments and it has already been discussed that assays for testing binding to TRAF2 are disclosed. Accordingly, applicant has supplied an adequate written description for the entire genus of claim 2. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

If and when the examiner decides to present an enablement rejection, applicant will provide its detailed response. It is applicant's position, however, that the present claims also fully comply with the enablement requirement, as it would not involve undue experimentation to produce sequences with random mutations that retain at least 95% identity and then test for binding activity. This can be done in a high throughput manner and is well within the skill of the art. It is no less enabling than the case of finding monoclonal antibodies as was found to be enabled in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Just because experimentation may be substantial does not mean that it is necessarily "undue". As long as it is routine

experimentation, those of ordinary skill in the art would readily be able to determine every sequence that falls within the scope of the claims, or whether any given sequence falls within the scope of the claims. Accordingly, it is urged that the examiner reconsider the possibility of issuing an enabling requirement and find at least claims 40 and 43 to be in condition for allowance.

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 USC 112. Reconsideration and allowance are hereby earnestly solicited.

Respectfully submitted,

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